DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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February 15, 2002

WARNING LETTER
CIN-WL-10371-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John B. Gerlach, Jr., CEO
Lancaster Colony
37 W. Broad Street
Columbus, Ohio 43215-4132

Re.: Quality Bakery Company
50 N. Glenwood Avenue
Columbus, Ohio

T. Marzetti Distribution Center
5800 North Meadows Drive
Grove City, Ohio

Dear Mr. Gerlach:

During an inspection on August 29-31, 2001 of the referenced companies that are owned by your firm, our Investigator collected labels for caviar products that are manufactured and distributed by the companies. Our review of the label collected for the product listed below shows that it causes the product to be in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

RAMANOFF BLACK LUMPFISH CAVIAR (7 oz. Net Wt. Jar)

The above product is misbranded within the meaning of Section 403(i)(2) because it contains color ingredients in addition to FD&C Yellow No. 5 and the label fails to declare the presence of these other colors as required by Sections 403(i)(2) of the Act and 21 CFR 101.22(k). FDA laboratory analysis of the caviar found the product to contain color additives that are subject to certification by FDA. Certified colors must be declared in the ingredient statement in descending order of predominance by their common or usual name (e.g., FD&C Blue No. 1, Red No. 40, Yellow No. 5).

Seafood HACCP Deviations

The FDA inspection also revealed that your firm has serious deviations from the Seafood HACCP regulations, Title 21 Code of Federal Regulations, Part 123. These deviations cause your firm's Black Whitefish Caviar, Black Lumpfish Caviar, and Red Lumpfish Caviar to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plans for pasteurized Whitefish (Caviar) and Pasteurized Lumpfish (Caviar) do not list the food safety hazard of Allergens/Additives. Your firm adds FD&C Yellow No. 5 to your caviar products and has listed that additive on the labeling of your products. You must include controls in your plan to assure that all of your products that include FD&C Yellow No. 5, regardless of the concentration, are appropriately labeled.

You must also have a HACCP plan that lists the critical control points, to comply with 21 CFR 123(c)(3). However, your firm's HACCP plans for Pasteurized Whitefish (Caviar) and Pasteurized Lumpfish (Caviar) do not list the critical control points of Receiving and Refrigerated Storage to control the food safety hazard of pathogen growth and toxin formation. During processing, caviar is subjected to significant manipulation by hand, which allows for the introduction of Staphylococcus aureus into the roe and caviar. Salting reduces competitive microorganisms and creates additional opportunities for S. aureus, which is tolerant to increased salinity, to reproduce and produce toxins that are heat stable. Your firm must assure that the products you receive have been adequately cooled during transport and storage to prevent pathogen growth.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels or in your seafood HACCP plans. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110). Other label violations can subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA. You also have the responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result in enforcement action such as seizure and/or injunction being initiated by FDA without further notice.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Your response should also outline the specific things you are doing to correct your Seafood HACCP deviations. You may wish to include in your response documentation such as corrected HACCP plans, test results, and/or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097.

Sincerely,

Mary L. Wenske for

Henry L. Fielden
District Director
Cincinnati District

Cc: Larry G. Noble, President
T. Marzetti Company
3838 Indianola Avenue.
Columbus, Ohio 43232